**THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| Appellant(s): | Ream et al. |
| Appl. No.: | 09/286,818 |
| Conf. No.: | 5472 |
| Filed: | April 6, 1999 |
| Title: | PHARMACEUTICAL CHEWING GUM FORMULATIONS |
| Art Unit: | 1618 |
| Examiner: | Hawes, P.A. |
| Docket No.: | 112703-035 |

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPELLANTS' APPEAL BRIEF**

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on April 6, 2006. This Appeal is taken from the Final Rejection in the Office Action dated January 11, 2006.

## I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Wm. Wrigley Jr. Company by virtue of an Assignment dated July 1, 1999 and recorded at reel 010060, frame 0375 in the United States Patent and Trademark Office.

## II. RELATED APPEALS AND INTERFERENCES

Applicants previously filed a Notice of Appeal filed on July 28, 2003 and an Appeal Brief on September 29, 2003 for the currently pending U.S. Pat. Application Serial No. 09/286,818. The Appeal was taken from the Final Rejection dated April 7, 2003. In the decision dated September 10, 2004, the Board of Patent Appeals and Interferences vacated the Examiner's rejection in the Final Office Action dated April 7, 2003 and entered a new rejection under 35 U.S.C. §112, second paragraph. The previously pending claims have since been amended.

## III. STATUS OF CLAIMS

Claims 1-12, 19-22 and 26-29 are pending in the above-identified patent application. Claims 13-18 and 23-25 were previously canceled. Claims 1-12, 19-22 and 26-29 stand rejected. Therefore, Claims 1-12, 19-22 and 26-29 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

## IV. STATUS OF AMENDMENTS

A Final Office Action was mailed on January 11, 2006. Appellants filed a Response with no amendments to the claims on March 7, 2006 in reply to the Final Office Action. An Advisory Action was mailed on March 30, 2006. In the Advisory Action, the Response was considered but was deemed not to place the patent application in condition for allowance. A copy of the Final Office Action is attached as Exhibit A in the Evidence Appendix, and a copy of the Advisory Action is attached as Exhibit B in the Evidence Appendix.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the drawings and specification for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a method for delivering a medicament to an individual (page 4, lines 6-10), the method comprising the steps of: providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof (page 10, line 21 to page 13, line 29), and at least one medicament (page 8, line 29 to page 10, line 3), the ingredients and medicament having a uniform distribution throughout the chewing gum (page 14, lines 5-10) including less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect (page 6, lines 12-14; page 7, lines 27-32; page 8, lines 2-4); chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual (page 4, lines 9-14; page 7, line 20 to page 8, line 28); and continuing to chew the chewing gum thereby creating a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual (page 4, lines 9-14; page 7, line 20 to page 8, line 28).

Independent Claim 7 is directed to a method for reducing the amount of agent necessary to achieve an effect in an individual as compared to a typical agent that is swallowed (page 5, lines 1-5), the method comprising the steps of: providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof (page 10, line 21 to page 13, line 29), and at least one agent that is typically swallowed by an individual to achieve a specific effect (page 8, line 29 to page 10, line 3), the ingredients and agent being uniformly distributed throughout the chewing gum (page 14, lines 5-10), the chewing gum including less than a typical amount of agent that is swallowed by the individual to achieve a bioequivalent effect (page 6, lines 12-14; page 7, lines 27-32; page 8, lines 2-4); chewing the chewing gum and thereby causing the agent to be released into the saliva of the individual (page 4, lines 9-14; page 7, line 20 to page 8, line 28); and continuing to chew the chewing gum forcing the agent through an oral

mucosa contained in a buccal cavity of the individual (page 4, lines 9-14; page 7, line 20 to page 8, line 28).

Independent 19 is directed to a method of delivering a medicament (page 4, lines 6-10), the method comprising the steps of: providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof (page 10, line 21 to page 13, line 29), and at least one medicament (page 8, line 29 to page 10, line 3), the ingredients and medicament being uniformly distributed throughout the chewing gum (page 14, lines 5-10), the chewing gum including less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect (page 6, lines 12-14; page 7, lines 27-32; page 8, lines 2-4); and chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum (page 4, lines 9-14; page 4, line 23).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the citations above, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

## VII. ARGUMENT

### A. LEGAL STANDARDS

#### 1. Definiteness under 35 U.S.C. § 112, second paragraph

The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, ¶ 2 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc,* 1 U.S.P.Q. 2d 1081-1088 (Fed. Cir. 1986). "If the claims, read in light of the Specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the Courts can demand no more." *North American Vaccine Inc. v American Cyanamid Co.,* 28 U.S.P.Q. 2d 1333, 1339 (Fed. Cir. 1993). In this regard, "[p]atent law allows the inventor to be his own lexicographer ... [T]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification. *United States v. Teletronics, Inc.,* 8 U.S.P.Q. 2d 1217, 1220 (Fed. Cir. 1988). By statute, 35 U.S.C. 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention." *In re Pilkington,* 162 U.S.P.Q. 145, 148 (C.C.P.A. 1996).

### B. THE CLAIMED INVENTION

Independent Claims 1, 7 and 19 recite, in part, that the claimed chewing gum includes less than a typical amount of medicament than is swallowed by an individual to achieve a bioequivalent effect. For example, chewing gum ingredients and one or more medicaments are distributed throughout the chewing gum. The amount of the medicament chosen to be used in the gum is less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect. During chewing of the chewing gum, the medicament is released from the chewing gum composition into the buccal cavity of the individual. Continued chewing of the chewing gum thereby creates a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

B. CLAIMS 1-12, 19-22 AND 26-29 ARE SUFFICIENTLY DEFINITE TO SATISFY THE REQUIREMENTS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-12, 19-22 and 26-29 are rejected because the Examiner alleges that the phrase "less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect" is unclear as to what amount is necessary for use in the claimed chewing gum. In response Appellants respectfully submit that the skilled artisan would find the scope of present claims clear in view of the specification.

Appellants respectfully submit that the Examiner is failing to consider the claimed invention as a whole. Appellants respectfully disagree with the Examiner's assertion that it is unclear what amount of aspirin (e.g. medicament) falls within the "less than typical amount" because one cannot determine the exact typical amounts of aspirin to treat headaches or heart conditions since this amount depends on age, weight, gender and other factors that are patient and population dependent. See, Office Action, page 3. The claimed "less than typical amount" of medicament in the chewing gum is modified by the claimed phrase "that is swallowed by the individual to achieve a bioequivalent effect." This is easily determined.

Aspirin is provided all the time in certain dosage forms depending on the desired treatment. For example, treating headaches in an adult male requires typically two tablets of aspirin, a known amount. Using aspirin to treat heart disease requires typically one aspirin, usually a baby aspirin, depending on the physician providing the treatment, which is another known amount. Whatever the typical amount that would be swallowed by a consumer, the claimed methods involve providing an individual a chewing gum having an amount of medicament that is less than that amount to achieve the bioequivalent effect.

To further corroborate Appellants' position, an Affidavit under 37 C.F.R. §1.132 of Ronald Ream ("*Affidavit*" attached as Exhibit C) was previously submitted. Regarding Mr. Ream's professional credentials (as detailed in the *Affidavit*), Mr. Ream has over 30 years of experience researching and developing food/drugs and technologies regarding same.

As supported by the *Affidavit*, one having ordinary skill in the art one would understand that in view of the specification the phrase "less than the typical amount of medicament than is

swallowed by the individual to achieve a bioequivalent effect" refers to a smaller effective amount of medicament provided in the claimed chewing gum that can achieve the same bioequivalent effect as a larger typical or standard amount of that same medicament that is swallowed (e.g. in a tablet or capsule). The typical or standard amounts of a medicament or active agent given in capsule or tablet forms are usually pre-determined standard amounts in a given industry (e.g. pharmaceutical, food) known by the skilled artisan for achieving a particular objective (e.g. alleviate a headache, increase alertness).

The specification teaches that the claimed invention is intended to apply to a wide range of drugs and agents (page 8, lines 22-33), and one of ordinary skill in the art would understand that absolute amounts of the active agents in gum can depend upon the agent given and the result to be achieved. While exemplary amounts have been provided in the specification in certain instances, for example, at page 9 at lines 1-25, as indicated at page 9, lines 26-31, exact dosing regimens will depend on the agent or medicament, the person taking the medicament and the desired result just as it does with all types of medicaments.

Appellants respectfully disagree with the Examiner's assertion that one having ordinary skill in the art would not be able to determine what the various typical dosage amounts would be for all types of medicaments because the amount is determined based on the needs of the patient population being treated. See, Office Action, page 4, lines 1-4. As discussed previously, the lower bioequivalent amount of medicament in a chewing gum would always be correlated to a specified amount of medicament that is typically swallowed for a certain effect.

For example, assume an individual wants to take two aspirin tablets containing a total of 500 mg to treat his mild headache. Instead, the claimed method involves giving the individual a chewing gum having an aspirin amount less than 500 mg (e.g. 300 mg) and still achieve the bioequivalent effect as if the individual has swallowed two aspirin tablets totaling 500 mg aspirin because of the adsorption through the oral mucosa.

Assume an individual wants to take two aspirin tablets containing a total of 750 mg to treat his headache because it's more severe. Instead, the claimed method involves giving the individual a chewing gum having an amount less than 750 mg (e.g. 500 mg) and still achieve the bioequivalent effect.

Just as the typical dosage forms of the medicament tablet or capsule may vary depending on the individual's desire or need, so to can the medicament amount in the chewing gum.

Indeed, the chewing gums can be provided to individuals based on the corresponding amount of medicament in tablet or capsule form they desire and still contain the bioequivalent yet lower dosage. Moreover, the smaller amounts needed in the chewing gum to achieve the bioequivalent of the desired or typical dosage forms can be readily determined through routine experimentation.

In addition, the skilled artisan is readily capable of determining what "typical amounts" of a medicament or drug given in a tablet or capsule form are for specific individuals. For example, for FDA approved drugs, typical or standard amounts would be the approved amounts. The FDA approved drugs are specific as to the type of individual (e.g. age, weight, illness) to receive them. In fact, the typical or standard amounts of a medicament are generally pre-defined and uniform in the pharmaceutical or food industry and are patient specific. Otherwise, how could any medicament be dispensed to the public at large or a physician or other healthcare provider determine how much of any pharmaceutical compound to dispense unless specific effective amounts of a drug were standardized for individuals. The literature is replete with documentation on what is typically or commonly administered to treat a certain type of disorder. Consequently, those skilled in the art readily know or can determine what this amount is.

As supported by the *Affidavit*, the amount of medicament used in the gum formulation of the claimed methods could clearly be the amount that delivers the bioequivalent of an approved dosage and will be less than the standard amount of that approved dosage given in a capsule or tablet because of the improved absorption efficiency through the oral mucosa. Where different dosages are approved and used, gum compositions having varying lower medicament amounts would deliver bioequivalent amounts for the different approved dosages. For other agents, typical or standard amounts can easily be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography.

Finally, the specific amount of an medicament agent incorporated into a gum for delivering a bioequivalent amount will be less than the pre-determined amount given in a tablet or capsule and can be readily ascertained by one skilled in the art using available methods. For instance, Appellants respectfully submit that the numerous examples and experiments set forth in the specification demonstrate the claimed methods using chewing gum having less than the typical amount of a medicament to achieve a bioequivalent effect of a swallowed medicament.

This is demonstrated with the caffeine study of Experiment 2 comparing the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed methods than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater bioequivalent effect. In fact, Appellants are able to achieve a equivalent bioavailability utilizing an oral drug delivery system that approaches that of a parenteral administration. These types of experiments can be similarly repeated to determine, for example, how much lower the amount of any medicament can be in a chewing gum to still obtain the same bioequivalent effect (e.g. bioavailability in the bloodstream) as swallowing the same medicament. As a result, the claimed methods can utilize a corresponding chewing gum having a lower medicament concentration for providing health effects similar to swallowing a larger dose of the same medicament, for example, in capsule or tablet form.

In sum, Appellants respectfully submit that those skilled in the art would understand the metes and bounds of the present claims when read in light of the specification and experimental examples. Accordingly, Appellants respectfully submit that 1, 7 and 19 and Claims 2-6, 8-12, 19-22 and 26-29 that depend from Claims 1, 7 and 19 fully comply with 35 U.S.C. §112, second paragraph, and are in condition for allowance.

## VIII. Conclusion

Appellants' claimed invention set forth in Claims 1-12, 19-22 and 26-29 are definite under 35 U.S.C. §112, second paragraph. Accordingly, Appellants respectfully submit that the rejection under 35 U.S.C. §112, second paragraph, is erroneous in law and in fact and should therefore be reversed by this Board.

A check in the amount of $500 is submitted herewith to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-35 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29156

Dated: June 7, 2006

## CLAIMS APPENDIX

## PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 09/286,818

1. A method for delivering a medicament to an individual, the method comprising the steps of:

providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof, and at least one medicament, the ingredients and medicament having a uniform distribution throughout the chewing gum including less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect;

chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual; and

continuing to chew the chewing gum thereby creating a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

2. The method of Claim 1 wherein the chewing gum is chewed for at least 2 minutes.

3. The method of Claim 1 wherein the chewing gum creates a saliva content of medicament of approximately 1700 to about 4400 ppm.

4. The method of Claim 1 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; and cardiovascular agents.

5. The method of Claim 1 including the steps of chewing a chewing gum including the medicament at least twice a day.

6. The method of Claim 1 wherein the chewing gum creates a saliva content of medicament of approximately 4 ppm to about 450 ppm.

7. A method for reducing the amount of agent necessary to achieve an effect in an individual as compared to a typical agent that is swallowed, the method comprising the steps of:

providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof, and at least one agent that is typically swallowed by an individual to achieve a specific effect, the ingredients and agent being uniformly distributed throughout the chewing gum, the chewing gum including less than a typical amount of agent that is swallowed by the individual to achieve a bioequivalent effect;

chewing the chewing gum and thereby causing the agent to be released into the saliva of the individual; and

continuing to chew the chewing gum forcing the agent through an oral mucosa contained in a buccal cavity of the individual.

8. The method of Claim 7 wherein the agent is a medicament.

9. The method of Claim 8 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; and cardiovascular agents.

10. The method of Claim 7 wherein the chewing gum is chewed for at least 2 minutes.

11. The method of Claim 7 wherein the chewing gum creates a saliva content of medicament of approximately 15 to about 440 ppm.

12. The method of Claim 7 including the steps of chewing a chewing gum including the medicament at least twice a day.

19. A method of delivering a medicament, the method comprising the steps of:

providing a chewing gum comprising ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors and combinations thereof, and at least one medicament, the ingredients and medicament being uniformly distributed throughout the chewing gum, the chewing gum including less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect; and

chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum.

20. The method of Claim 19 wherein the medicament is chosen from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; and cardiovascular agents.

21. The method of Claim 19 including the steps of chewing a chewing gum including the medicament at least twice a day.

22. The method of Claim 19 wherein two pieces of chewing gum are chewed at a time.

26. The method of claim 1 further comprising adjusting the hydrophilic/lipophilic balance of the medicament.

27. The method of claim 1 further comprising blending the medicament with a base/emulsifier system.

28. The method of claim 27 wherein the blending occurs before the providing.

29. The method of claim 19 further comprising absorbing through an oral mucosa of the individual an effective amount of the medicament into the systemic system of the individual.

## EVIDENCE APPENDIX

EXHIBIT A: Office Action dated January 11, 2006

EXHIBIT B: Advisory Action dated March 30, 2006

EXHIBIT C: Affidavit under 37 C.F.R. §1.132 of Ronald Ream

## RELATED PROCEEDINGS APPENDIX

None

# EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/286,818 | 04/06/1999 | RONALD L. REAM | P99.0082 | 5472 |

29156 7590 01/11/2006

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

| EXAMINER | |
|---|---|
| HAWES, PILI ASABI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 01/11/2006

Due: 4-11-06

Please find below and/or attached an Office communication concerning this application or proceeding.

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JAN 16 2006

ATTY MMB-TSB
DOCKET # 10303-035

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/286,818 | REAM ET AL. | |
| | Examiner | Art Unit | |
| | Pili A. Hawes | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12,19-22 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 19-22, 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Summary*

Receipt of Applicant's Remarks filed 10-31-2005 is acknowledged. Claims 1-12 and 19-22 and 26-29 are pending in this action. As set forth in the previous office action, Claims 1-12 and 19-22 and 26-29 are rejected.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 19-22 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amend the claims to delete the phrase "less than the enteral administration amount" to recite "less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect". This amendment is not sufficient to overcome the rejection as set forth in the previous office action or as set forth by the Board of Patent Appeals and Interference Decisions on Appeal mailed 09-10-2004.

The rejection is not overcome for the following reasons:

The Board as set forth on pages 4 and 5, describe various amounts of aspirin formulations. One of ordinary skill in the art would be aware that aspirin is used for the treatment of headaches as well as for preventing heart attacks, and the amount of

aspirin for the treatment of these ailments vary. It is unclear what amount of aspiring fall with in the "less than typical amount" since one cannot determine the exact typical amounts of aspirin to treat headaches or heart conditions since this amount depends on age, weight, gender, and other factors that are patient and population dependent. Thus the metes and bounds of what a typical amount is, is not defined in a manner sufficient to make one of ordinary skill understand what amounts constitute a typical amount, thus the "less than typical amount" can also not be determined.

Likewise, the Board as set forth on page 6, discuss the specification example given as support for their being sufficient explanation of a "typical amount" using the chewing gum formulation with 50 mg of caffeine in comparison with the 100 mg oral tablet dosage. The Board set forth that "even assuming, therefore, that the 'typical amount' of caffeine administered is 100 mg, the specification provides no basis on which to extrapolate that dosage to other agents or medicaments." This argument is still applicable over the instant claims, even though applicants have added the phrase "that is swallowed by the individual to achieve a bioequivalent effect" because there is no basis for determining from the specification what the typical amount would be for all the various types of medicaments. Examiner notes that claim 1 recited a method of delivering a medicament. This is a generic term that encompasses all known medicaments. One of ordinary skill in the art would recognize that a typical dosage is determined based on many factors such as gender, age, weight, and medical conditions. Thus a typical amount for one patient population might be different than a typical amount from another patient population with differing sets of factors and

illnesses. Thus it is not within the level of one of ordinary skill to be able to determine what the various typical dosage amounts would be for all the medicaments known to man, as that amount would needs be determined based on the needs of the patient population being treated.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

# EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/286,818 | 04/06/1999 | RONALD L. REAM | P99.0082 | 5472 |

29156 7590 03/30/2006

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

| EXAMINER | |
|---|---|
| HAWES, PILI ASABI | |
| ART UNIT | PAPER NUMBER |
| 1615 | |

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action Before the Filing of an Appeal Brief | Application No. 09/286,818 | Applicant(s) REAM ET AL. | |
|---|---|---|---|
| | Examiner Pili A. Hawes | Art Unit 1615 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 10 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: the phrase "less than a typical amount" is indefinite for all types of medicaments since each type of medicament has a different "typical amount" thus one of ordinary skill in the art would not be able to universally apply this to all types of medicaments based on the teachings of the instant specification and claims. The specification may offer guidance for some medicaments such as caffeine or apirin, but does not offer guidance of what a typical amount is for other medicaments.

# EXHIBIT C

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| Applicant(s): | Ream et al. |
| Appl. No.: | 09/286,818 |
| Conf. No.: | 5472 |
| Filed: | April 6, 1999 |
| Title: | PHARMACEUTICAL CHEWING GUM FORMULATIONS |
| Art Unit: | 1615 |
| Examiner: | Hawes, P.A. |
| Docket No.: | 112703-035 |

**AFFIDAVIT UNDER 37 C.F.R. § 1.132**

Sir:

I, Ronald Ream, hereby state as follows:

1. My experience and qualifications are as follows:
   - B.S. in Chemistry from Northern Illinois University – 1964
   - M.B.A. from Loyola University in Chicago – 1970
   - Advanced Certificate in Food Science from Illinois Institute of Technology – 1974
   - 40 years of work experience with 30 years related to foods/drugs

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated January 11, 2006 pending against the above-identified patent application. As one having ordinary skill in the art, I believe that the scope of the presently pending independent Claims 1, 7 and 19 is clearly understood by the skilled artisan in view of the specification and the examples.

4. The claimed invention of the above-identified patent application relates to a method for delivering a medicament to an individual. The method comprises, in part, providing a chewing gum having at least one medicament. The medicament has a uniform distribution

throughout the chewing gum that is less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect. The gum is chewed to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual. The continued chewing of the gum thereby creates a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

5. Applicants have surprisingly found that less medicament or agent can be placed in the chewing gum than is typically orally administered and swallowed by an individual to achieve the same bioequivalent effect due to the absorption of the medicament through the oral mucosa. In fact, Applicants have surprisingly found that in certain instances, for at least certain drugs and agents, the administration of the medicament or agent using chewing gum through the buccal cavity can provide an increased effect even as compared to parenteral administration.

6. The specification provides explicit guidance for assisting one having ordinary skill in the art to determine the scope the present claims. For example, the specification teaches the enhanced absorption of medicaments through the oral mucosa by using chewing gum. Oral administration of drugs is by far the most common method. When administered orally, the drugs are typically ingested or swallowed, and drug absorption usually occurs due to the transport of cells across the membranes of the epithelial cells within the gastrointestinal tract. A further issue effecting the absorption of orally administered drugs is the form of the drug.

7. One having ordinary skill in the art would understand that most orally administered drugs or medicaments are given in the form of tablets or capsules. The tablets or capsules contain a pre-determined concentration of medicament depending on the specific objectives of the medicament and the recipient of the medicament. The pre-determined amount is generally an approved FDA amount of a medicament or a standard amount commonly used in the relevant pharmaceutical or food industry. The standard amount of medicaments in capsules or tablets can also be identified by one having skill by reading the ingredient listing on a package insert or by testing using various analytical techniques such as chromatography. As a result, the

amount of medicament typically administered to achieve a desired effect or to treat a particular disorder is known or is readily ascertainable by those skilled in the art.

8. The experiments set forth in the specification provide further guidance for achieving a bioequivalent effect using a lesser amount of a medicament in a chewing gum versus the typical or standard amount of the same medicament in a tablet. For example, the caffeine study of Experiment 2 demonstrates that the administration of the medicament or agent via a chewing gum through the buccal cavity can provide an increased effect than when the same medicament or agent is swallowed in tablet form. The study compares the bioequivalent effect/bioavailability of caffeine in consumers' bloodstream after chewing caffeine containing gum versus swallowing caffeine pills. These examples demonstrate that less caffeine can be provided in the claimed product than that that is typically ingested, for example, through No Doze, and still achieve as good if not greater effect on a consumer. Experiment 4 demonstrates that the chewing gum agents are indeed adsorbed in the oral cavity.

9. For all the foregoing reasons, as one having ordinary skill in the art, I believe that Applicants' specification and the experimental examples allow the skilled artisan to determine the metes and bounds of the presently pending claims.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 3/2/06

Name: Ronald Ream